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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,465	02/10/2004	Shivshankar Sundaram	N9136	1376
23456	7590	12/01/2005		
WADDEY & PATTERSON 1600 DIVISION STREET, SUITE 500 NASHVILLE, TN 37203			EXAMINER PATEL, MITAL B	
			ART UNIT	PAPER NUMBER
			3743	
DATE MAILED: 12/01/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/775,465

Applicant(s)

SUNDARAM ET AL.

Examiner

Mital B. Patel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-9, 15-27 is/are rejected.
- 7) ☒ Claim(s) 5 and 10-14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment/Arguments

1. Applicant's arguments filed 5/27/05 have been fully considered but they are not persuasive.
2. In response to applicant's argument that a spacer is attached to an inhaler and is external to the device, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.
3. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the spacer is not an integral part of the inhaler) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).
4. In response to Applicant's arguments with respect to the spray inlet being distal to a second body and that the first and second bodies are proximal to the spray inlet, it should be noted that the terms proximal and distal are relative terms and the Examiner has interpreted the claims in the broadest reasonable scope.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 3, 4, 6, 9, 15, 17, 18, 20, 21, 22, 23, 24, 25, 26, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Braithwaite (US 6,347,629).

3. **As to claim 1**, Braithwaite teaches a spacer for delivering medication spray into the lungs of a patient comprising a first body (**that formed by 94,98**) having a large diameter distal end and a small diameter proximal end; a second body (**that formed by 92**) having a large diameter distal end and a small diameter proximal end joined to the distal end of the first conical body; a mouthpiece **99** positioned at the proximal end of the first body; a spray inlet **at 45** positioned at a distal end of the second body; and the first body further comprising a first internal chamber and the second conical body comprising a second internal chamber, the first and second internal chambers forming a spray conduit having a continuous spray passage from the spray inlet to the mouthpiece (**See Fig. 9**).

4. **As to claim 2**, Braithwaite teaches a spacer further comprising a plurality of air inlets **90** passing through the first body, the air inlets positioned downstream from the spray inlet near the distal end of the first conical body.

5. **As to claim 3**, Braithwaite teaches a spacer wherein the plurality of air inlets are evenly spaced around the first body (**See Fig.9**).

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6. **As to claim 4**, Braithwaite teaches a spacer wherein the first body includes a large diameter distal end surface and wherein the air inlets are positioned in the large diameter distal end surface (**See Fig.9**).

7. **As to claim 6**, Braithwaite teaches a spacer wherein each the first body and second body have a conical geometry (**See Fig.9**).

8. **As to claim 9**, Braithwaite teaches a spacer for delivering a medication spray ejected by an inhaler to the lungs of a patient through the patient's mouth, the spacer comprising a conduit (that formed by **92,94,98**) having a proximal end and a distal end; a spray inlet **at 45** attached to the distal end of the conduit, the spray inlet adapted for receiving medication spray from the inhaler; a mouthpiece **99** attached to the distal end of the conduit, the conduit including at least one interior chamber defining a continuous spray passage from the spray inlet to the mouthpiece; and at least one air inlet **90** passing through the wall of the conduit, the air inlet positioned downstream from the spray inlet.

9. **As to claim 15**, Braithwaite teaches a spacer apparatus for transmitting medication to patients, comprising a mouthpiece **99** ; a first chamber (formed by **94,98**), the first chamber having a proximal end connected to the mouthpiece; a second chamber (formed by **92**), the second chamber having a proximal end connected to the distal end of the first chamber; a spray inlet **at 45** connected to a distal end of the second chamber, the spray inlet adapted to receive medication spray, and an internal spray path defined from spray inlet to the mouthpiece, through the first chamber and second chamber.

10. **As to claim 17**, Braithwaite teaches a spacer apparatus further comprising a plurality of air inlets **90** passing through the apparatus into the first chamber.
11. **As to claim 18**, Braithwaite teaches a spacer apparatus wherein the first chamber and the second chamber are converging chambers, wherein a diameter of the proximal ends of each chamber are smaller than a diameter of the proximal ends of each chamber (**See Fig. 9**).
12. **As to claim 20**, Braithwaite teaches a spacer apparatus wherein the plurality of air inlets are circular (**See Fig. 9**).
13. **As to claim 21**, Braithwaite teaches a spacer apparatus for distributing medication to patients, comprising; an air chamber (**formed by 92, 94, 98**) defining an air passage therethrough, the air chamber having an upstream end and a downstream end, wherein a plurality of air inlets **90** are positioned between the upstream end and the downstream end.
14. **As to claim 22**, Braithwaite teaches a spacer apparatus further comprising an adapter **91** proximate the spray inlet, the adapter functional to receive a spray outlet from a medication dispenser.
15. **As to claim 23**, Braithwaite teaches a spacer for facilitating the delivery of a medication spray from a medication spray dispenser to the mouth of a patient, the spacer comprising: spray inlet means **at 45** to receive the medication spray; a mouthpiece **99**; spacer walls defining at least one internal chamber and further defining a conduit means (**formed by 92,94,98**) fluidly connecting the spray inlet to the mouthpiece; and means **90,100,101** to generate spray recirculation zones proximate the

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conduit means, the recirculation zones functional to inhibit contact between the medication spray and the spacer walls.

16. **As to claim 24**, Braithwaite teaches a spacer, the spacer walls defining first (formed by **94,98**) and second internal chambers (formed by **92**).

17. **As to claim 25**, Braithwaite teaches a spacer apparatus, the means for generating high-pressure recirculation zones comprising a closed chamber **100,101** proximal to the spray inlet and at least one air inlet **90** in the first internal chamber downstream of the spray inlet.

18. **As to claim 26**, Braithwaite teaches a method of delivering a medication spray into the lungs of a patient using a spacer, the method comprising: directing the medication spray into a spray inlet end **at 45** of the spacer; using the medication spray and spacer geometry to generate high-pressure recirculation zones **at 100,101** inside the spacer; and using the high-pressure recirculation zones and the external airflow to direct the medication spray away from walls of the spacer and out of a mouthpiece end of the spacer.

19. **As to claim 27**, Braithwaite teaches a method further comprising delivering air into the spacer through air inlets **90** positioned downstream from the spray inlet.

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

22. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

23. Claims 7, 8, 16, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Braithwaite (US 6,347,629).

24. **As to claims 7 and 8 and 19**, Braithwaite teaches essentially all of the limitations except for wherein the first and second bodies have an elliptical shape or oblong shape and wherein the air inlet is oblong. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to make the shape of the bodies and air inlet of Braithwaite of any particular

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geometric shape because Applicant has not disclosed that the specific geometry provides an advantage, is used for a particular purpose, or solves a stated problem.

One of ordinary skill in the art, furthermore, would have expected Braithwaite's bodies having the conical shape and the air inlet being circular, and applicant's invention, to perform equally well because both geometric shapes would perform the same function of reducing the particle size of the medicament and providing a passageway for air.

Therefore, it would have been prima facie obvious to modify Braithwaite to obtain the invention as specified in claims 7 and 8 and 19 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Braithwaite.

25. **As to claim 16**, Braithwaite teaches essentially all of the limitations except for wherein at least a portion of one of the first or second chambers is collapsible.

However, on page 11, of the specification Applicant discloses that the spacer may be collapsible, which implies that the collapsibility aspect of the spacer is not a critical and essential part of the invention. As such one of ordinary skill in the art would expect the spacer of Braithwaite to perform equally as well regardless of whether or not the spacer is collapsible because the function of the spacer is not altered as a result of whether or not it is collapsible.

Allowable Subject Matter

26. Claims 5 and 10-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

27. The following is a statement of reasons for the indication of allowable subject matter: As to claim 5 and 10, the prior art of record does not teach nor render obvious the overall claimed combination of a spacer further comprising a unidirectional valve functionally positioned within the spray passage proximate the mouthpiece, wherein the valve allows the patient to inhale but not exhale through the spray passage in the spacer.

Conclusion

28. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 571-272-4802. The examiner can normally be reached on Monday-Friday (11:00-7:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mital B. Patel
Primary Examiner
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